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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/603,943	06/26/2003	Kouji Hattori	239612US0	3410

22850 7590 09/01/2005

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EXAMINER

CHANG, CELIA C

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 09/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/603,943	Applicant(s) HATTORI ET AL.	
	Examiner Celia Chang	Art Unit 1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 and 10-21 is/are pending in the application.
- 4a) Of the above claim(s) 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 1-4, 7, 10 and 19-21 is/are rejected.
- 7) ☐ Claim(s) 5 and 11-18 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Amendment and response filed by applicants dated Jun. 14, 2005 have been entered and considered carefully. Claims 8-9 have been canceled. Claim 6 stayed withdrawn. Claims 1-5, 7, 11 and newly added claims 12-21 are pending.

2. Applicants' election of Group I claims 1-5, 7, 9-11 being drawn to the scope wherein A is phenyl, B is phenyl or naphthyl were examined. The remaining scope were withdrawn from consideration. The restriction has been made final. Applicants are advised that the non-elected scope should be deleted from the claims.

3. Claims 1-5, 7, 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Please note that the newly added proviso finds no antecedent basis in the specification. Any negative limitation or exclusionary proviso must have basis in the original disclosure. In re Johnson 195 USPQ 187. Ex parte Grasselli 231 USPQ 393.

Please note that contrary to attorney's allegation, claims 1-5 as originally filed provided no support for at least one of R5 and R8 is selected.....etc. Especially, it is noted that claims 2-8 has the explicit limitation that R8 is H or loweralkyl. No support on both R5 and R8 are lower alkyl or R5 and R8 can both be hydrogen. Especially, in the specification, exclusive disclosure

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of di-substituted compounds on the B ring is considered a teaching away from the instantly amended proviso that both R5 and R8 are hydrogen. In re Baird 29 USPQ2d 1550.

Removal of all new matter is required. In re Russmussen 210 USPQ 325.

4. The rejection of claims 1-5 under 35 USC 102(b) over CA 111:77643 or Shuker et al. CA 127:277798 is maintained for claims 1-4 and 19-21. Because when new matter is removed and the claim is restored to the non-amended version, the rejection still applies.

3. The rejection of claims 1-5 under 35 USC 103(a) over Humaus et al. '946 is maintained for claims 1-4 and 19-21 for reason of record.

Please note that even in the amended version, the instant claims differ from Humaus et al. '946 compounds by one methyl i.e. when one of R5 or R8 is C1-alkyl. The one methyl addition compounds are considered structurally obvious over the known compounds.

5. Claim 10 is rejected since the claim is inoperative and therefore lacks utility. Please note that claim 10 as now amended lacks utility since agonizing receptor *without* any physiopathological effect on subject has no utility.

Claim 10 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed is inoperative as discussed above and one skilled in the art clearly would not know how to use the claimed invention.

Please note that state of the art references evidenced that the "utility" of a compound employing the β 3-adrenergic receptor is compound and disease oriented. For example, the

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diarylalkylaminoalkanols of CA 132:194184 has effect on reducing intravesical pressure; the benzodioxoles of CA 1126:1213 have anti-ocular hypertension effect; the phenylsulfonamides of Ca 124:116877 have effect in treating diabetes and obesity. Therefore, each individual compound is responsible for the specific efficacy in treating specific disorder even though the β 3-adrenergic receptor were involved in the mechanism.

The instant specification while provided description on page 14 that the instantly claimed compounds have inhibition of intravesical pressure of urethral orifice, no nexus nor enablement can be found for the instant chemical structure for the "claimed" scope of agonizing any and all β 3-adrenergic receptors.

6. Claims 5, 11-18 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

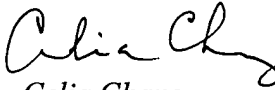
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8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Celia Chang whose telephone number is 571-272-0679. The examiner can normally be reached on Monday through Thursday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang, can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

OACS/Chang
Aug. 25, 2005


Celia Chang
Primary Examiner
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